SUPPORTING STATEMENT FOR INFORMATION COLLECTION
"VOLUNTARY REGISTRATION OF COSMETIC PRODUCT ESTABLISHMENTS"
OMB No. 0910-0027

Part A. – JUSTIFICATION.

1. Circumstances Which Make This Information Collection Necessary.

The Federal Food, Drug, and Cosmetic Act (the act) (Attachment A) provides FDA with the responsibility for assuring consumers that cosmetic products in the United States are safe and properly labeled. Cosmetic products that are adulterated under section 601 of the act (21 U.S.C. 361) or misbranded under section 602 of the act (21 U.S.C. 362) may not be distributed in interstate commerce. To assist FDA in carrying out its responsibility to regulate cosmetics, FDA has developed the Voluntary Cosmetic Registration Program (VCRP). The VCRP requests, in part, that establishments that manufacture or package cosmetic products register with FDA on Form FDA 2511, "Registration of Cosmetic Product Establishment" (Attachment B).

Voluntary registration of cosmetic product establishments was proposed in a petition filed with FDA by the Cosmetic, Toiletry, and Fragrance Association (CTFA), announced in the Federal Register of August 26, 1971 (36 FR 16934). In response to the petition, FDA issued regulations establishing a voluntary registration procedure in a final rule published in the Federal Register of April 11, 1972 (37 FR 7151).

The information requested on Form FDA 2511 includes the name and address of the cosmetic product establishment, all business trading names used by the cosmetic product manufacturer, and the type of business (manufacturer and/or packer). Specific instructions for filling out Form FDA 2511 are on the back of the form (Attachment B).

The regulations describing the voluntary registration of cosmetic product establishments are found in 21 CFR part 710 (Attachment A) under the following section headings:

§710.1 Who should register.
§710.2 Time for registration.
§710.3 How and where to register.
§710.4 Information requested.
§710.5 Amendments to registration.
§710.6 Notification of registrant; cosmetic product establishment registration number.
§710.7 Inspection of registrations.
§710.8 Misbranding by reference to registration or to registration number.
§710.9 Exemptions.

2. How, By Whom, and the Purpose for Collecting This Information.

This information is collected by submission of Form FDA 2511 to FDA's Office of Cosmetics and Colors (OCAC). Form FDA 2511 is available on FDA's VCRP website at http://www.cfsan.fda.gov/~dms/cos-regn.html.

Because registration of cosmetic product establishments is not mandatory, voluntary registration provides FDA with the best information available about the locations, business trade names, and types of activity (manufacturing or packaging) of cosmetic product establishments. FDA places registration information for cosmetic product establishments in a computer data base and uses the information to generate mailing lists for distributing regulatory information and for inviting firms to participate in workshops on topics in which they may be interested. FDA also uses the information for estimating the size of the cosmetic industry and for conducting on-site establishment inspections. Registration is permanent, although FDA requests that respondents submit an amended Form FDA 2511 if any of the originally submitted information changes.

Information from the data base is releasable to the public under FDA compliance with the Freedom of Information Act (FOIA).

3. Use of Technology to Reduce the Burden on the Public.

Completion of Form FDA 2511 requires no compilation or arrangement of data and can be completed with a typewriter or pen. Form FDA 2511 may be submitted by mail or by computer-printed facsimile.

FDA continually seeks ways to reduce the reporting burden through advances in information technology. Currently, FDA is working on establishing a web based format for accepting cosmetic product establishment data. Submission capability by this medium will reduce the reporting burden for respondents and FDA.

4. Identification and Use of Duplicate Information.

To the best of FDA's knowledge, no other federal government agency is engaged in the collection of this information.

5. FDA's Efforts to Reduce Burden on Small Businesses.

This information collection will not have a significant economic impact on small businesses. Small businesses usually can complete Form FDA 2511 just by providing the company name and address. FDA aids small businesses in complying with registration requirements through its administrative and scientific staffs. FDA's Small Business Guide is available on FDA's website at http://www.fda.gov/oc/industry/.

6. Impact of Not Collecting This Information or Collecting Information Less Frequently.

Registrations of cosmetic product establishments are submitted only once and therefore cannot be collected less frequently. Amended registrations are submitted occasionally, for example when a cosmetic product establishment site moves or the corporate structure changes.

7. Explain any special circumstances that occur when collecting the information.

There are no special circumstances involving this information collection. Submission of information is voluntary.

8. Identification of Outside FDA Sources.

In accordance with 5 CFR 1320.8(d), FDA published a 60-day notice for public comment in the Federal Register of February 27, 2004 (69 FR 9339) (Attachment C). No comments were received.

FDA frequently solicits feedback from cosmetic product establishments regarding their registrations with FDA. No adverse comments have been received.

9. Payment or Gifts Offered to Respondents.

There are no payments or gifts provided to respondents.

10. Method of Ensuring Respondent Confidentiality.

None of the information supplied on Form FDA 2511 is confidential. OCAC personnel forward a copy of a submitted registration to the FDA district office responsible for on-site cosmetic product establishment inspections and return a validated copy to the cosmetic product establishment for which the form was submitted. The public and other interested parties may request copies under the provisions of the FOIA.

11. Use of Sensitive Questions.

This information collection does not use sensitive questions.

12. Burden Hours and Cost Associated With This Information Collection.

(a) Hour burden estimate

The hour burden estimate for this information collection, which is the estimated annual burden for reporting this information to FDA, is 6 hours per year. From fiscal year (FY) 2001 to FY 2003, FDA received an average of 15 registration submissions per year. Using information from industry personnel, FDA estimates that submission of Form FDA 2511 requires 0.4 hour (25 minutes) per person to complete.

Table 1 summarizes the estimated annual reporting burden for this information collection.

Table 1. –Estimated Annual Reporting Burden						
21 CFR Part	Form	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
710	FDA 2511	15	1	15	0.4	6

(b) Hour Cost Burden

The annual hour cost burden to respondents is approximately $168. FDA estimates the cost by using an hourly wage of $28 per hour (corresponding to a GS-12, step 1, federal government hourly salary); 6 burden hours times $28 per hour equals $168.

13. Annual Cost Estimate to Respondents.

There are no capital costs or operating and maintenance costs associated with this collection of information.

14. Annual Cost Estimate to FDA.

FDA estimates that 0.05 professional staff persons per year (100 hours) are needed to process submitted forms and maintain computer files. Using an hourly wage of $28 per hour, FDA estimates the annual staff cost to be $2800. FDA orders 1500 copies of preprinted Form FDA 2511 for use over three years. The unit cost of the 5-part preprinted form is approximately $.10, for an annual cost of $50.00. FDA estimates annual computer costs to be $350. Therefore, FDA estimates the total annual cost to FDA for this information collection is $3200.

15. Changes from Previous Approval.

The VCRP was suspended during FY 1998 due to a lack of budgetary funding and was reinstated at the beginning of FY 1999. The estimated hour burden is 30% of the previous level reported in 2000. In general, the larger cosmetic companies have resumed participating in the program, whereas the smaller companies are lagging.

The estimated hour burden cost is 42% of the previous level reported in 2000. The hour burden cost includes estimated cost of living increases.

16. Publishing the Results of This Information Collection.

No comprehensive tabulation of the data is planned or anticipated.

17. Reason for Not Displaying the OMB Approval Date.

FDA has no reason for not displaying the OMB approval date.

18. Explanations to Section 19, "Certification for Paperwork Reduction Act Submissions."

There are no exceptions to the certification statement identified in Item 19 of OMB Form 83-I, "Certification for Paperwork Reduction Act Submissions."

Part B. – COLLECTIONS OF INFORMATION USING STATISTICAL METHODS.

This information collection does not use statistical methods.

Attachment A

Statutes and Regulations

Attachment B

Form FDA 2511

Attachment C

60-Day Notice for Public Comment